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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/439,429 11/15/99 POWER

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HM12/1102

EXAMINER

EPPS, J

ART UNIT

PAPER NUMBER

1635

DATE MAILED:

11/02/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
09/439,429

Applicant(s)

POWER et al.

Examiner  
Janet Epps

Group Art Unit  
1635



☒ Responsive to communication(s) filed on Aug 15, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 3-16 is/are pending in the application

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 3-16 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Art Unit: 1635

## **DETAILED ACTION**

### ***Status of Claims***

1. The Double Patenting rejection of claims 5-6 are withdrawn in response to Applicant's filing of a terminal disclaimer on 8-30-00. The rejection of claim 9 under 35 USC 112, second paragraph and 35 USC 101 is withdrawn in response to Applicant's arguments.
2. Claims 5-6, and 11-12 are rejected under 35 USC 112, second paragraph for the reasons given below in the rejection necessitated by Applicant's amendment.
3. Claims 3-4, and 7-16 remain rejected under 35 USC 112, first paragraph for the reasons set forth in the Office Action mailed 5/10/00.

### ***Response to Arguments***

4. Applicant's arguments filed 8-15-00 regarding the rejection of claims 3-16 have been fully considered but they are not persuasive.
5. Regarding the rejection of claims 3-4, 7-10 and 13-16 under 35 U.S.C. 112, first paragraph, Applicants state that they have attached a paper by Applicants that disclose that the *in vivo* use of the method as set forth in the present application does perform as indicated in the *in vitro* studies. However, there was no paper by Applicants attached to Applicant's response filed 8-15-00. Furthermore, since the *in vivo* methods described in Applicant's paper are not supported by Applicant's specification, and since the date of Applicant's publication is unknown, it is unclear if one of skill in the art would not have been able to practice the *in vivo* method described by Applicant's publication at the time of filing of the instant application.

6. Applicant's arguments with respect to claims 5 and 11-12 have been considered but are moot in view of the new ground(s) of rejection.

***Rejection Necessitated by Applicant's amendment***

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 5-6, and 11-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5-6 and 11-12 recite "antisense oligonucleotide comprising an exon targeting sequence flanking donor splice sites thereby regulating expression of TNF- $\alpha$ ". This phrase is since it unclear how an exon targeting sequence within an antisense oligonucleotide could be flanked by multiple donor splice sites situated within the mRNA target of the antisense oligonucleotide. Furthermore, the phrase "thereby regulating expression of TNF- $\alpha$ " used in this context is vague and indefinite since it is unclear how the description of the composition of the antisense oligodeoxynucleotide results in the regulation of TNF- $\alpha$  expression.

***New Grounds of Rejection***

9. Claims 13-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claim 13 recites "the steps of targeting", and "the tumor necrosis factor alpha splice region", there is lack of antecedent basis for these limitation in this claim.
11. Claim 14 recites "the step of administering" in claim 13, there is lack of antecedent basis for this limitation in the claim.
12. Claims 15-16 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting an essential step, such omission does not set forth the method in clear and unambiguous terms. See MPEP § 2172.01. The omitted step is a correlation, or recapitulation step at the end of the claim which restates the preamble.
13. Claim 16 recites the limitation "the step of administering" in claim 15. There is insufficient antecedent basis for this limitation in the claim.

#### ***Claim Rejections - 35 USC § 102***

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

15. Claim 5 is rejected under 35 U.S.C. 102(e) as being anticipated by Nyce et al.

Claim 5 reads on a synthetic nuclease resistant antisense oligodeoxynucleotide for selectively inhibiting human tumor necrosis factor alpha (TNF- $\alpha$ ) comprising an exon targeting sequence flanking donor splice sites. Although there is some ambiguity regarding the exact

sequence applicants are referring to, this claim is interpreted as reading on synthetic antisense oligodeoxynucleotides targeting intron-exon borders of human TNF- $\alpha$ .

Nyce et al. disclose synthetic antisense oligonucleotides comprising a variety of modifications that would render the oligonucleotide nuclease resistant (see entire document). For example, Nyce et al. describe the use of a "3'-end cap" strategy by which nuclease-resistant linkages are substituted for phosphodiester linkages at the 3' end of the oligonucleotide to protect the oligonucleotide from degradation (see col. 4, line 1-65). The oligonucleotides of Nyce et al. may be targeted to a variety of mRNAs for the treatment of lung conditions, including human TNF-alpha (col. 3, lines 24-25). In addition, the antisense oligonucleotides of Nyce et al. may be targeted to intron-exon borders of the mRNA targeted.

Nyce et al. teach each and every aspect of the instant invention thereby anticipating Applicant's claimed invention.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps whose telephone number is (703) 308-8883. The examiner can normally be reached on Monday through Friday from 8:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Elliott, can be reached at (703) 308-4003. The fax number for this group is (703) 305-7939.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet L. Epps, Ph.D.

October 25, 2000

  
ROBERT A. SCHWARTZMAN  
PRIMARY EXAMINER